



# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

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Indianapolis, Indiana 46204  
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[www.IN.gov/idem](http://www.IN.gov/idem)

## VIA CERTIFIED MAIL

Bruce Carter, P.E., President  
American Medical Waste Professionals, Inc. (AMPRO)  
616 South 4<sup>th</sup> Street  
Elkhart, Indiana 46516-2770

Re: Approval of Infectious Waste Treatment Facility  
Solid Waste Facility Permit FP 20-09  
American Medical Waste Professionals, Inc.  
Elkhart County

Dear Mr. Carter:

American Medical Waste Professionals, Inc. (AMPRO), is hereby issued solid waste facility permit FP 20-09, pursuant to IC 13-15-1-3 and 329 IAC 11-9 *et seq.* This approval is based on the solid waste processing facility permit application submitted to the Indiana Department of Environmental Management (IDEM), on January 30, 2007, dated January 29, 2007, and the following subsequent amendments and addendums to the application: the April 12, 2007 response, received April 16, 2007, to IDEM's March 20, 2007 request for additional information (RAI); a May 31, 2007 site visit; and information on good character and needs. This permit issuance authorizes AMPRO to construct and operate an infectious waste treatment facility and is subject to the terms of this letter and the enclosed requirements and conditions.

The solid waste processing facility referenced above is located at 616 South 4<sup>th</sup> Street, Elkhart, Indiana 46516 in Elkhart County. It contains approximately 0.75 acres of land. It is part of the north half of Section 8, Township 37 North, Range 5 East, Concord Township, in the city of Elkhart, Indiana. The facility includes one (1) autoclave for steam treatment of the infectious waste. The autoclave processing capacity is limited to eight (8) tons per day.

In accordance with 329 IAC 11-11-4, solid waste facility permit FP 20-09 does not authorize: any injury to any person or private property; the invasion of other private rights; the infringement of federal, state, or local laws or regulations; nor preempt any duty to comply with other state or local requirements.

IDEM may modify or revoke this permit in accordance with 329 IAC 11-11-6, and/or take enforcement action against the owner, operator, and/or permittee herein for failure to comply with the requirements and conditions of this permit.

In accordance with 329 IAC 11-11-1(c), this permit will not become effective until: (1) all financial responsibility documents have been executed and delivered to IDEM in the form and amount specified in Requirement F2 of this permit letter, and (2) any real estate transfers necessary to vest legal title of the real estate upon which the permitted activity is to occur in the name of the owner listed on the application have been completed, executed, and recorded and documents evidencing such transfer have been delivered to IDEM or proof of the applicant's agreement regarding the leasing of this property has been submitted to IDEM.

In accordance with 329 IAC 11-11-3, this permit is valid through June 15, 2012. To continue operation past this period, a renewal application in accordance with 329 IAC 11-9-4 must be submitted a minimum of one hundred twenty (120) days prior to the expiration date of the permit.

Pursuant to IC 4-21.5, a Petition for Review of this permit letter may be initiated by you, as applicant, or by an "aggrieved or adversely affected person". This permit becomes effective once all applicable time periods for petitioning for Stays of Effectiveness have expired, unless you are notified in writing by an Environmental Law Judge that the permit has been further stayed. As discussed in our enclosed Notice of Decision, if you wish to challenge this decision, you must file a Petition for Review with the Office of Environmental Adjudication within eighteen (18) days from the date that this permit letter was mailed, pursuant to IC 4-21.5-3-7.

If you have any questions regarding this matter, please call (800) 451-6027, press 0 and ask for John Hale, or ask for extension 2-8871 or dial 317-232-8871.

Sincerely yours,

Thomas Linson, Chief  
Permits Branch  
Office of Land Quality

Enclosure: Notice of Decision  
Letter to the Elkhart Public Library  
Letter to the Elkhart Truth  
Letter to the South Bend Tribune  
Letter to the IDEM Northwest Regional Office

cc: Elkhart County Health Department (with enclosure)  
Elkhart County Commissioners (with enclosure)  
Elkhart County Solid Waste Management District (with enclosure)  
The Honorable David L. Miller, Mayor of Elkhart (with enclosure)  
IDEM Northern Regional Office (with enclosure)

## **PERMIT REQUIREMENTS**

- A. General Permit Requirements**
- B. Construction Requirements**
- C. Pre-Operational Requirements**
- D. Operational Requirements**
- E. Closure Requirements**
- F. Financial Responsibility for Closure**



## **A. GENERAL PERMIT REQUIREMENTS**

- A1. It is recommended that all required submittals be printed double-sided and sent via certified mail. All reports, notifications, ground water reports, and other information required to be submitted by this permit should be sent to:

**John Hale  
Permits Branch, Mail Code 65-45  
Office of Land Quality, Room N1154  
Indiana Department of Environmental Management  
100 North Senate Avenue  
Indianapolis, Indiana 46204-2251**

- A2. The American Medical Waste Professionals, Inc. (AMPRO) infectious waste treatment facility (facility) shall operate in accordance with the applicable requirements of 329 IAC 11 and as detailed in the RAI response dated April 12, 2007, and received April 16, 2007, and other parts of the application, where not specifically addressed in this permit.
- A3. Any additional infectious waste processing systems cannot be constructed without first receiving a modification of this permit.
- A4. The following requirements apply to insignificant modifications at the facility:
- a. The permittee may not be required to apply for a minor or a major modification of the current permit from IDEM if proposing one of the insignificant modifications described in Requirements A4(b) below.
  - b. If the permittee proposes or is required to make one of the following insignificant modifications, the permittee shall submit documentation of the proposed insignificant modification to IDEM via certified mail prior to making the modification:
    - (1) Changes in the waste water handling or disposition procedures or both.
    - (2) Alterations to the drainage around the facility, except for normal maintenance.
    - (3) Changes in the facility layout.
    - (4) A change in a piece of equipment that is not identical, but is functionally equivalent.
    - (5) Any modification to the permitted facility that IDEM determines will improve the operation of the facility without significantly altering the approved solid waste processing facility permit.

The documentation must include a detailed description of the proposed project.

- c. If IDEM determines that the modification under Requirement A4(b) is a major or minor modification, the permittee will be notified in writing within thirty (30) days after receipt of the documentation by IDEM, that the permittee must submit an application for a minor or major modification to the current permit if the permittee wishes to still make the modification.
- d. If the permittee does not receive notification from IDEM within thirty (30) days

after IDEM's receipt of the documentation as required by Requirement A4(b), the permittee may initiate the insignificant modification in accordance with documentation provided to IDEM.

- e. No permit modification shall be required for an insignificant modification that is required to:
  - (1) correct operational violations under this article; or
  - (2) protect human health and the environment.
- A5. The permittee shall report to IDEM any event which may cause an imminent and substantial endangerment to human health or the environment. This information must be reported orally to IDEM within twenty-four (24) hours from the time the permittee becomes aware of the event. The permittee shall also provide a written report to IDEM within five (5) days of the time of the event. The report shall include for each event: date and time, possible causes, actions taken or planned to correct, reduce, eliminate, and prevent recurrence of the event.

## **B. CONSTRUCTION REQUIREMENTS**

- B1. The ground surface around the facility must be properly sloped, graded, and maintained to promote proper surface water run-off and to prevent ponding of water.
- B2. The facility shall be constructed according to the plans submitted to IDEM. Any changes in the plans must be submitted to and approved by IDEM.
- B3. The permittee shall comply with 329 IAC 11-12-2, including construction and installation of equipment for storage, processing, and handling of the infectious waste. Approval to install the autoclave and construction described in the permit application for the infectious waste processing facility is granted, subject to the requirements of this permit. The permittee shall be able to furnish onsite any documentation needed to prove that all the local permits necessary to operate the processing facility have been obtained.

## **C. PRE-OPERATIONAL REQUIREMENTS**

- C1. The permittee shall comply with the requirements of 329 IAC 11-12 (Operational Approval and Pre-Operational Requirements).
- C2. Three (3) consecutive pre-operational biological tests must be performed, reported as described in the April 12, 2007 RAI response, and approved by IDEM. The tests must meet the 4 log<sub>10</sub> kill standard for effective treatment of infectious waste using *Bacillus stearothermophilus* spores or its equivalent as a biological indicator at the maximum weight loading that is to be allowed.
- C3. The permittee shall notify IDEM in writing when all applicable pre-operational requirements as specified in 329 IAC 11-12-2(1) through (3) have been completed at the facility. Unless IDEM denies operational approval within fourteen (14) days of receipt of such notice, the facility may begin to accept solid waste in accordance with its permit.
- C4. The permittee shall establish and submit financial assurance for closure as specified in Section F of this permit, prior to commencing operation at the facility.

## **D. OPERATIONAL REQUIREMENTS**

- D1. The processing facility must be operated to comply with 329 IAC 11-13-1 for access control, 329 IAC 11-13-2 for on-site roads, 329 IAC 11-13-3 for signs, 329 IAC 11-13-4 for sanitation, 329 IAC 11-13-5 for safety requirements, and 329 IAC 11-13-6 for records and reports.
- D2. At least once, the permittee must request and receive verification from each generator that the generator has a process or procedures which are designed to prevent inclusion of mercury wastes in the infectious waste autoclaved at the facility. Generators desiring further information on mercury separation, elimination, identification, reclaiming, or recycling may consult the IDEM Office of Pollution Prevention and Technical Assistance (OPPTA) at 800/988-7901 or 317/232-8172; their hospital information website at <http://www.in.gov/idem/compliance/ctap/sectors/hospitals/index.html>; or the American Dental Association web site on Best Management Practices for Amalgam Waste at [http://www.ada.org/prof/resources/topics/topics\\_amalgamwaste.pdf](http://www.ada.org/prof/resources/topics/topics_amalgamwaste.pdf)
- D3. Operators are required to have training to recognize hazardous waste, to properly handle and use personal protective equipment when handling infectious waste, and to operate the autoclave. Facility personnel involved in the processing and handling of infectious waste shall follow approved procedures for handling and disposal of infectious waste and also OSHA and Indiana State Department of Health requirements.
- D4. Manifests for infectious waste equivalent to those required for municipal waste in 329 IAC 11-15-3,4, and 5 are required for shipments of infectious wastes sent for processing at the facility. A manifest is to be generated for each load of the treated waste and delivered to the solid waste disposal or processing facility receiving the treated waste as required by 329 IAC 11-15-4.
- D5. Quarterly tonnage reports for the infectious waste and solid waste received at the processing facility must be submitted to IDEM as required by 329 IAC 11-14-1.
- D6. Infectious waste may be processed in the autoclave, except for noted exclusions. The infectious waste that is delivered for processing shall constitute infectious waste as defined in 329 IAC 11-2-18. 329 IAC 11-2-18 defines infectious waste to include (1) Pathological wastes, including tissue, organs, body parts, and blood or body fluids in liquid or semi liquid forms that are removed during surgery, biopsy, or autopsy. (2) Biological cultures and associated biologicals. (3) Contaminated sharps. (4) Infectious agent stock and associated biologicals. (5) Blood and blood products in liquid and semi liquid form. (6) Laboratory animal carcasses, body parts, and bedding. (7) Wastes (as defined in 410 IAC 1-3-19). As used in this rule, "waste" means any solid liquid, or semi-liquid material that is discarded or being accumulated prior to being discarded or that has served its natural, biological, medical, or intended purpose and is generally discarded and not reused.

The infectious waste delivered for processing must be able to be legally processed in the autoclaves, and all waste must be properly packaged in containers in accordance with local, state, and federal regulations.

- D7. Hazardous waste as defined by the U. S. EPA under the Resource Conservation and Recovery Act of 1976, asbestos waste, antineoplastic waste or chemotherapy waste, and packaged waste identified as variant Creutzfeldt-Jakob Disease, Creutzfeldt-Jakob Disease, or Mad Cow Disease waste shall not be processed in the autoclave. Radioactive material that exceeds three (3) times background radiation levels, after forty-eight (48) hours of storage, shall not be processed in the autoclave. If hazardous or asbestos waste is evident in the infectious waste to be processed in the autoclave, or if the waste exceeds the radioactivity limit, it must be returned to the generator for proper disposal, and a report is to be issued to IDEM as detailed in 329 IAC 11-21-6. Antineoplastic or chemotherapy waste, and packaged waste associated with variant Creutzfeldt-Jakob Disease, Creutzfeldt-Jakob Disease, or Mad Cow disease must be transferred for off-site processing.

Autoclave processing is excluded for pathological waste of recognizable human body parts such as an amputated human arm, leg, or head, or a torso that may be of a size to not be properly treated by limited exposure to steam, could create an aesthetic concern for workers moving the bins of infectious waste that have been processed, or a potential concern at the landfill to accept the treated infectious waste. Separation of the body parts that are to be cremated is to be done at the hospital or generating facility.

- D8. All requirements of 329 IAC 11-21-10, such as infectious waste warning signage, transportation, and packaging must be followed, except for the following exception to the maximum duration for storage or containment: The refrigerated storage or containment for excluded pathological or infectious waste is limited to thirty (30) days at a temperature not to exceed 45° Fahrenheit. If operational problems, obnoxious odors, putrescent waste, or potential health or environmental problems, develop from the thirty (30)-day refrigerated storage limit, the storage limit will be lowered to seven (7) days, unless an intermediate storage limit is agreed to in discussions with IDEM. Treated infectious waste in the compactor bin must be removed from the site the following operating day after it has been filled, except for holidays and weekends, or within seven days of starting to fill the bin for partially filled bins. Reusable containers for infectious waste must be thoroughly washed and decontaminated each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by using disposable liners, bags, or other devices that are removed with the infectious waste. AMPRO autoclave equipment that comes into contact with infectious waste shall be disinfected before infectious waste personal protective equipment is no longer required to be worn in the area of the equipment. If solid waste comes into contact with the infectious waste, it must be treated as infectious waste.
- D9. Storage for infectious waste and storage for solid waste shall be limited to the areas delineated in the application. Storage is limited to the refrigerated trailer storage for excluded pathological waste, antineoplastic or chemotherapy waste, and packaged waste associated with variant Creutzfeldt-Jakob Disease, Creutzfeldt-Jakob Disease, or Mad Cow disease.
- D10. The Turbo Machine Corporation autoclave that is six (6) feet in diameter by fifteen (15) feet long is to be used. The autoclave design rate will be determined in pre-operational tests, but is expected to be near 1,200 pounds/hour. The waste charging for each autoclave is not to exceed the amount validated in the pre-operational tests. The date,



time, and weight of infectious waste charged to the autoclave are to be recorded.

- D11. Waste shall not be charged or removed from the autoclave until the internal autoclave pressure is equal to atmospheric pressure. The steam, and operation of the autoclave is to be controlled such that the infectious waste in the autoclave is exposed to a minimum temperature of 285° F or greater that is maintained at a pressure of forty (40) psig or greater and is maintained for a minimum of twenty five (25) minutes.
- D12. The autoclave temperature and pressure shall be monitored and recorded at least every two (2) minutes during autoclave operation. As required by 329 IAC 11-1-3, the records are to be kept for at least five (5) years. All recording equipment shall be calibrated and maintained according to the manufacturers' specifications for the duration of the permit. Records shall be kept to demonstrate that recording equipment are being properly maintained and calibrated.
- D13. The following parameters must be monitored and recorded, at the locations indicated.

<u>Parameter</u>	<u>Location</u>
Autoclave temperature	Internal autoclave thermocouple
Lb/in <sup>2</sup> gauge pressure	Internal autoclave pressure
Waste feed rate	Waste bin weights from the scale

- D14. The bins of infectious waste, which have been treated in the autoclave so that pathogenic qualities of the waste have been reduced for safe handling, may be tipped inside the building into the compactor chute to the enclosed, exterior roll-off container. Alternatively, the bins may be tipped using a device such as a fork lift with a rotator into a waste container inside the processing building as described in the July 19, 2007 Addendum to the AMPRO application document. The receiving container must be covered with a lid or tarp before leaving the building. The treated waste must be disposed of in a permitted solid waste land disposal or processing facility approved to accept the solid waste, such as a municipal solid waste landfill, an incinerator, a pyrolysis unit, or an equivalent facility.
- D15. Weekly biological tests for each autoclave must be performed for quality assurance purposes as described in Section V, C of the April 12, 2007 RAI response received April 16, 2007, and the test results reported to IDEM quarterly. The biological test data must meet the 4 log<sub>10</sub> kill standard for effective treatment of infectious waste. More stringent operating conditions, equipment repair, or other appropriate actions are required if the quality assurance test results note a departure from normal results that approaches a test failure or results in a test failure. A test failure is an abnormal condition which shall be reported to IDEM within 24 hours as required by permit condition A5.
- D16. Any abnormal operating condition which causes potential exposure to infectious waste, any violation of operating requirements established in the permit, any unscheduled shutdown of the autoclave or associated equipment, or any damage to the autoclave or associated equipment that if not repaired could result in exposure to infectious waste or result in exceeding a requirement specified in the permit, must be reported verbally to

IDEM within twenty-four (24) hours of its occurrence, and must appear in a quarterly written report to IDEM. The quarterly report must list the date and time of each occurrence as described above, its cause, its rectification, its approximate duration, and the type and magnitude of the problem. Based on review of the information, if IDEM determines that a given event was in fact due to routine items inherent in the operation of the facility which are not indicative of poor operation/maintenance, then it will not be deemed a violation of this permit.

- D17. 329 IAC 11-21-8 requirements must be followed for maintaining clean facility floors by directing floor wash-down water to a sanitary sewer.
- D18. Based upon review of operating data, inspections of the facility, or other considerations, IDEM may require modifications to the operating limits set forth in this permit.
- D19. A waste disposal contingency plan complying with 329 IAC 11-9-2(j)(6) is to be implemented if the facility is unable to operate for more than a continuous twenty-four (24)-hour period as required by 329 IAC 11-13-7. In the event of an emergency, breakdown or unplanned shutdown of the facility equipment, or other event which materially impedes proper management or processing of the infectious waste, the deliveries of infectious waste that would exceed the facility's storage capacity need to be rerouted to an approved third party disposal site or directed to another facility with permitted disposal capacity for infectious waste. Normal delivery of infectious waste shall resume when safe management and handling of infectious waste can be maintained.
- D20. Electronic waste shall be stored, transported, and managed in accordance with applicable state and federal regulations and as described in the application.

#### **E. CLOSURE REQUIREMENTS**

- E1. The permittee shall comply with 329 IAC 11-16-1 (Closure Requirements).
- E2. The permittee must close the facility in a manner that:
  - a. Minimizes the need for further maintenance:
  - b. Controls post-closure escape of contaminants to the ground surface, surface waters, ground waters or the atmosphere;
  - c. At a minimum is in compliance with all applicable requirements of this permit.
- E3. Final closure shall proceed in accordance with the permit application dated January 29, 2007, and received January 30, 2007, at tab 4 in section 1.0, except as specified otherwise in this permit. The post-closure monitoring described in the application is not required for this permit.
- E4. The permittee shall notify IDEM in writing at least fifteen (15) days prior to the intended date to begin closure of the processing facility. The final closure of the facility shall be initiated within seventy-two (72) hours after receiving the final volume of waste. The following closure activities shall be performed at the facility during the final closure:

- a. Notification must be given to all affected parties that the facility closed. A sign that references the nearest infectious waste processing facility must be established at the site.
  - b. All infectious waste or solid waste remaining, stored, or collected at the facility must be removed. The waste must be properly disposed of at a permitted facility. All storage containers and recyclable materials must be removed.
  - c. The autoclaves, waste receiving area, waste storage areas, and the general site must be cleaned so they are free of waste and contaminated liquid.
  - d. Wastewater in holding tanks must be removed if applicable. The wastewater must be pumped out and disposed of in accordance with local, State, and federal statutes and rules.
- E5. Waste that contains any significant putrescible component, or any other waste that may create pollution conditions, shall be removed from the facility within two (2) days of initiation of the facility final closure. All other closure activities shall be completed within ninety (90) days of initiation of the final closure activities.
- E6. The permittee shall submit to IDEM within thirty (30) days of closure a certification signed by the permittee which specifically identifies the closed facility and documents that the closure was performed in accordance with Requirements E1 through E5 of this permit. The certification shall also include the facility contact person during the post-closure care period, the person's name, address, and phone number.
- E7. The final closure will be deemed adequate unless within ninety (90) days of receipt of the certification required in Requirement E6 of this letter, IDEM issues a request for additional information for final closure, including additional action which needs to be taken and the timetable for the necessary additional action.

#### **F. FINANCIAL RESPONSIBILITY FOR CLOSURE**

- F1. The permittee shall adequately fund closure of the facility. Until final closure of the facility is certified, the permittee must annually review and submit to IDEM the updated financial closure estimate within thirty (30) days of each anniversary date of the original effective date of establishment of financial responsibility for closure. As a part of the annual review, the permittee must revise the closure estimates as listed in 329 IAC 10-39-2(c)(1)(A) and (B) and/or for any changes in the facility plans that may increase the cost of closure.
- F2. The permittee shall establish financial responsibility of closure similar to that provided for in 329 IAC 10-39 prior to beginning operations at the facility. The sum used for funding of the closure of the facility shall be the thirteen thousand four hundred eighty-six dollars (\$13,486) estimate of the Closure Cost Estimate in the original application. The permittee may revise the cost estimates by submitting a detailed cost analysis for closure of the facility. The revised cost estimates must be approved by IDEM prior to implementation of any changes in the originally approved fund. However, the sum of the closure cost estimate shall not be less than four thousand dollars (\$4,000) based on \$4,000 per acre or a fraction of an acre covered by the permitted facility and the

approximately 0.75 acres for the site.